



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,801	06/29/2001	Thomas C. Pinkerton	6794S-000019US	1264

7590 06/10/2004

Donald R. Holland
Harness, Dickey & Pierce, P.L.C.
Suite 400
7700 Bonhomme
St. Louis, MO 63105

EXAMINER

AZPURU, CARLOS A

ART UNIT PAPER NUMBER

1615

DATE MAILED: 06/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/897,801	PINKERTON, THOMAS C.	
	Examiner	Art Unit	
	Carlos A. Azpuru	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 85-92,94-102,105-113,116-136 and 138 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 85-92,94-102,105-113,116-136 and 138 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. 03/29/2004
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the amendment after final and remarks filed
03/30/04.

Applicant's request for reconsideration of the finality of the rejection of the last
Office action is persuasive and, therefore, the finality of that action is withdrawn.

The rejection under 35 USC 102(a) over D'Antonio is hereby withdrawn in view of
applicant's amendment.

The obviousness-type double patenting rejections are hereby maintained over
10/443,361, but is withdrawn over 09/606,909.

The following is a new rejection of the claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that
form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1615

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 85, 90, 91, 95, 96, 97, 99, 102, 106-108, 110, 113, 119, 121, 124-126, 129, 131, 134-136 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Pettis et al.

Pettis et al disclose a method for administration of a substance into the dermis as a bolus (see Abstract). Needles used in the claimed method are disclosed by Pettis et al at page 7, lines 15-28; and page 8, lines 1-3. Microneedle arrays are disclosed at page 2, lines 5-9; page 7, line 7. Delivery is into the dermis (see Abstract, page 1, lines 25-28). Heparin is specifically recited for delivery of this type (see page 8, line 9). The instant method is anticipated by Pettis et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1615

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims Claims 85, 90, 91, 95, 96, 97, 99, 102, 106-108, 110, 113, 119, 121, 124-126, 129, 131, 134-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pettis et al.

Pettis et al disclose a method for administration of a substance into the dermis as a bolus (see Abstract). Needles used in the claimed method are disclosed by Pettis et al at page 7, lines 15-28; and page 8, lines 1-3. Microneedle arrays are disclosed at page 2, lines 5-9; page 7, line 7. Delivery is into the dermis (see Abstract, page 1, lines 25-28). Heparin is specifically recited for delivery of this type (see page 8, line 9). Therefore, those of ordinary skill would have found it well within their skill to claim the instant method of administration by delivering a substance into the dermis given the teachings of Pettis et al. They would have further expected similar therapeutic results from the administration of drugs intradermally. There are no unusual and/or unexpected results which would rebut prima facie obviousness. As such, it would have been obvious to claim administration of a substance intradermally, and further to expect similar therapeutic results from the administration thereof given the teachings of Pettis et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

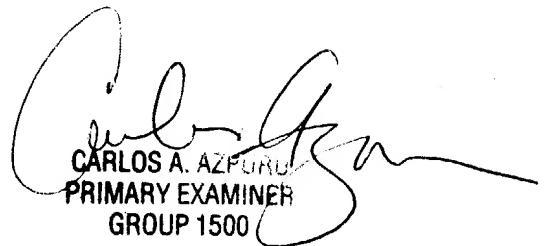
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone

Art Unit: 1615

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ca


CARLOS A. AZPURUA
PRIMARY EXAMINER
GROUP 1500